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December 2, 1999

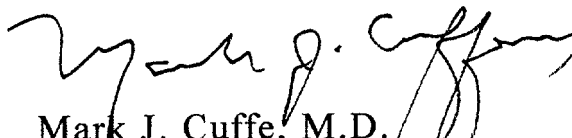
Document Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs,

This is a letter regarding Docket #97N-4846, which may allow the FDA to regulate some types of all~~o~~graft ~~bone~~ as medical devices. I wish to strongly object to this proposed FDA Regulation. I feel that the passage of this regulation would simply cause not only a shortage of vital bone products for patient care but also to greatly increase the cost of such products. Such allograft bone products are vitally important for the health and well-being of thousands of patient's in this county, and I do not feel that further federal regulation of ~~these~~ products is necessary.

Thank you for your time.

Sincerely,


Mark J. Cuffe, M.D.

MJC:cma

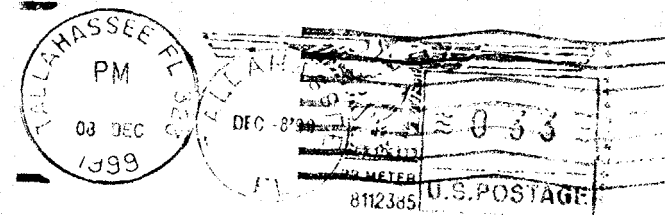
97N-4846

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